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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,816	05/15/2001	Andrew C. Braisted	9491-053-27 DIV	1579

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EXAMINER	
LUKTON, DAVID	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/854,816	BRAISTED ET AL.	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *1-3,6,7,10,13 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,5,8,9,11,12,14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-16 remain pending. Claims 1-3, 6, 7, 10, 13, 16 remain withdrawn from consideration. Claims 4, 5, 8, 9, 11, 12, 14, 15 are examined in this Office action.

. . . .

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-15 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 14 is drawn essentially to the following two embodiments:

1. A method of therapeutically treating a mammal which has been infected with HIV, with the objective of ameliorating symptoms and/or inhibiting viral replication

2. A method of therapeutically treating a mammal which is at risk of becoming infected with HIV, but which is not yet infected

This ground of rejection is directed at the second of these two possibilities.

Applicants have shown (page 72 of US 2002/0151473) that one or more peptides of the invention can inhibit viral replication *in vitro*. From this, applicants are proposing that they can therapeutically treat a mammal which has not yet been infected. This is interpreted to mean that applicants believe that they can prevent the infection from

occurring at all. However, the prospect of success in this regard is not supported by the simple *in vitro* experiment that has been performed. Perhaps the claimed peptides will be effective to reduce viral replication, in an infected mammal, from 100 (arbitrarily selected) units per day to 90 units per day. But this does not mean that viral replication can be prevented in the mammal who has not yet been exposed to HIV, but is about to be. For such a mammal, the viral replication could easily overwhelm the effects of the claimed peptide, leading to an infection. The infection may be less severe as a result of the peptide being present, but the notion that the infection can be prevented is without merit.

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

In view of the absence of working examples which would show the skilled artisan how to prevent HIV infection, and given the unpredictability in the art, "undue experimentation" would be required to prevent HIV infection.

✧

Claim 8 is objected to on grammatical grounds. In the third line from last, the following is recited:

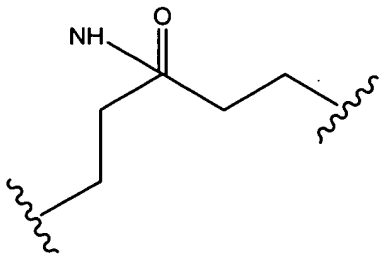
"...HIV clade, and amino acid substituted variant thereof"

It appears that the indefinite article ("an") should precede "amino acid".

✧

Claims 4, 5, 8, 9, 11, 12, 14 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Structure #6 of claim 4 contains the following (shown for the case of "r" and "q" both representing the integer 2):



As is evident, this structure contains a pentavalent carbon.

- In claim 4, structure 1, there are 5 hyphens to the left of "Z" and 4 hyphens to the right. In claim 4, structure 6, there are two hyphens to the left of "Z" and three hyphens to the right. In claim 4, structure 11, there are two hyphens to the left of "Z" and two hyphens to the right. What is the meaning of this, and in applicants opinion, what exactly is the difference between (a) a single horizontal line, and (b) a series of hyphens or dash marks? The best option for clarity would be to use just one horizontal line to signify a covalent bond.

- In claim 5, a "SEQ ID NO:" should be provided.

- Claim 8 makes reference to the form "gabcde", "defgab", etc. However, this is meaningless without reference to figure 18, and even then is somewhat cryptic.

It is suggested that at least some information from figure 18 be imported into claim 8, so that at least some meaning can be gleaned from the claim.

- Claim 9 is drawn to a compound of claim 8 that further comprises a group designated S'. However, claim 12 is not properly subgeneric to claim 8. The best option would be to cast claim 9 in independent form; alternatively claim 8 could be amended to make reference to variable S'.

- Each of claims 11, 12 and 14 is dependent on a non-elected claim (claim 10).

- Claim 11 is drawn to a compound in which "Z" is a peptide consisting of six amino acids of a consensus sequence as displayed in any of figures 16A-16G. However, it is not readily apparent which sequences are to be included and which are to be excluded. The best option would be to incorporate only the most relevant information from the figures into claim 11.

- Claim 12 is drawn to a compound of claim 8 or 10 that further comprises a second constrained helical peptide. However, claim 12 is not properly subgeneric to claim 8 or 10. Neither of claims 8 or 10 makes any mention of a second constrained helical peptide. The best option would be to cast claim 12 in independent form.

- Claim 14 is drawn essentially to the following two embodiments:

  1. A method of therapeutically treating a mammal which has been infected with HIV, with the objective of ameliorating symptoms and/or inhibiting viral replication

  2. A method of therapeutically treating a mammal which is at risk of becoming infected with HIV, but which is not yet infected

  This ground of rejection targets the second of these two possibilities. For the mammal which has not yet been infected, what would be the manifestations of a successful treatment; equally important, what would be the manifestations of an **un**successful treatment? Thus, suppose that one of the claimed peptides were administered to a person who had never been exposed to HIV, and who never will be. Would the absence of any infection constitute proof, in applicants opinion, that the compound is effective to treat a human who had not been exposed? Suppose that the experiment were repeated but that instead of administering one of the claimed compounds, physiological saline were

administered instead. In applicants opinion, would this constitute evidence that saline can prevent HIV infection?

✦

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. §102(b) as being anticipated by Bhatnagar (WO 92/09625).

Bhatnagar discloses (page 26) the following cyclic peptide (the two cysteines are in disulfide linkage):

Ac-Cys-Glu-Val-Glu-Asp-Gln-Lys-Cys-NH_2

Claim 11 permits one to take any of the sequences in figures 16A-G, and to then make an "amino acid substituted variant thereof". In other words, the sequences in figures 16A-G do not limit the claims at all, since one can replace 100% of the amino acids with other amino acids. The other point to be made is that claim 10 encompasses peptides that are cyclic by virtue of disulfide bonds.

Thus, the claim is anticipated.

✦

Claim 11 is rejected under 35 U.S.C. §102(b) as being anticipated by Jackson (*J Am Chem Soc* **113**, 9391, 1991)

Jackson discloses cyclic peptides containing the following sequence:

X-K-A-A-A-A-K-X

wherein "X" represents 2-amino-6-mercaptohexanoic acid, and wherein the thiol groups are bonded together in disulfide linkage. The explanation above (rejection over Bhatnagar) applies here as well.

Thus, the claim is anticipated.

✧

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

DAVID LUKTON, PH.D.
PRIMARY EXAMINER